

Applicants: Lutz Heuer et al.
Application No. 09/901,979
Response to Office Action dated February 9, 2005

REMARKS

Applicants respectfully requests reconsideration and allowance of this application in view of the following comments.

Claims 9, 11, 12 and 15 are pending.

Rejections under 35 U.S.C. 112, first paragraph

The Examiner rejected the claims under 35 U.S.C. 112, first paragraph, for failure to comply with the written description requirement. The Examiner found the specification fails to teach the ratios of components in the Declaration by Dr. Martin Kugler, of record. In response, Applicants submit that there is no requirement in the law that the specification support unclaimed limitations appearing in a Rule 132 Declaration. The written description requirement, by its very terms, requires that the specification contain a written description of "the invention." It is well settled in the patent law that "the invention" is what is claimed. The instant claims do not recite the particular ratios in the examples in the Kugler Declaration. Consequently, there is no requirement that the specification support these ratios. Moreover, the claims, which do not include these ratios, cannot be found to be in violation of the written description requirement because the specification does not support these unclaimed limitations. Respectfully, the Examiner's position on this point is untenable, and Applicants respectfully request that the Examiner reconsider and withdraw this rejection.

The instant specification teaches in the very first paragraph that the invention relates to synergistic mixtures containing cyproconazole. In addition, at page 9, lines 20 to 23, there is a teaching that cyproconazole can be combined with other active ingredients, and "[i]n many cases, this results in synergistic effect, that is to say, the activity of the mixture is greater than the activity of the individual components." That same section ends with a list of "particularly preferred components" for such mixture, and tebuconazole and propiconazole are mentioned at page 10, line 10. As if that were not enough, a second, narrower list of "particularly preferred components" is given at starting at the bottom of page 15, and here, again, both tebuconazole and propiconazole are mentioned at line 15. A person having ordinary skill in the art would understand that the invention related to synergistic mixtures of cyproconazole plus tebuconazole or propiconazole. While the specification does not recite the ratios in the examples of the Kugler Declaration, such ratios do not appear in the instant claims. Instead, the instant claims relate generally to synergistic mixtures of cyproconazole plus tebuconazole or propiconazole. There is ample support for such mixtures in the instant specification, and, therefore, the written description requirement is satisfied.

The Examiner rejected the claims under 35 U.S.C. 112, first paragraph, for failure to satisfy the enablement requirement. According to the Examiner, he found the specification does not reasonably provide enablement for synergistic compositions comprising cyproconazole plus tebuconazole or propiconazole. The Examiner concluded

that experimentation must be conducted in order to determine which ratios are synergistic in view of the Kull reference which was cited in Applicants' Declaration filed on July 22, 2002.

In response, Applicants submit the specification is in fact enabling to a person skilled in the art, wherein the instant specification discloses synergistic mixtures at page 1, line 6 and at page 9, line 21, wherein at least two of the azoles, tebucanazole and propiconazole, are contemplated at page 10. Moreover, the Examiner argues that "numerous experiments would need to be done" in view the Kull reference cited in the Declaration to support his position for lack of enablement, but he has not made any allegation based on any of the other factors as enumerated by the Federal Circuit in *In re Wands*. For the Examiner's reference, the factors are listed as follows:

- (A) The breadth of the claims;
- (B) The nature of the invention;
- (C) The state of the prior art;
- (D) The level of one of ordinary skill;
- (E) The level of predictability in the art;
- (F) The amount of direction provided by the inventor;
- (G) The existence of working examples; and
- (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

See MPEP §2164.01(a). Moreover, Applicants points out that:

It is improper to conclude that a disclosure is not enabling based on an analysis of only one of the above factors while ignoring one or more of the others. The examiner's analysis must consider all the evidence related to each of these factors, and any conclusion of nonenablement must be based on the evidence as a whole.

MPEP §2164.01(a). In the instant case, the Examiner appears to address only (H) in his rejection as evidenced by his reference to statement regarding experimentation, but ignores the others factors and therefore it is believed the Examiner has not considered all of the evidence as a whole. Even though the Examiner relies on the Kull reference, the Declaration from which Kull is referenced is not part of the specification, and therefore cannot be considered in making this rejection. The Declaration is provided as evidence for purposes of overcoming a rejection such as the obviousness rejection discussed *infra*. Accordingly, Applicants submit the Examiner has not made out a proper *prima facie* case for lack of enablement, and requests this rejection to be withdrawn.

Even if the Examiner were correct, which Applicants do not concede, Applicants refers the Examiner to MPEP §2164.01 which recites in part: "[t]he test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue." See *In re Angstadt*, 537 F.2d 498, 504, 190 USPQ 214, 219 (CCPA 1976). Applicants submit a person skilled in the *microbicial art* would

understand how to make the claimed invention in view of the specification without undue experimentation. The instant specification discusses various compositions related to the present invention and in the prior art. Applicants point out that "[w]hen analyzing the enabled scope of a claim, the teachings of the specification must not be ignored because claims are to be given their broadest reasonable interpretation that is consistent with the specification." MPEP §2164.08. Therefore, the instant specification discloses synergistic mixtures at page 1, line 6 and at page 9, line 21, wherein at least two of the azoles, tebucanazole and propiconazole, are contemplated at page 10. Applicants again refer the Examiner to the Declaration of Dr. Martin Kugler as evidence and support for the synergistic mixtures. Accordingly, Applicant submits the instant specification is in fact enabling to a person skilled in the art without undue experimentation.

Further on this point, Applicants point out that enablement is not precluded by the need for some experimentation, and, therefore, the fact that experimentation is required does not, in and of itself, necessitate a lack of enablement rejection. The question is whether the experimentation is undue, and, as pointed out above, the Examiner has not really made the necessary findings on this point. As the Court in *In re Wands*, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988), also explained, "[e]nablement is not precluded by the necessity for some experimentation such as routine screening." Further, on the same page, they quoted with approval the following quote from *In re Jackson*, 217 USPQ at 807 (POBA 1982):

“The test [for undue experimentation] is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction the experimentation should take. [Emphasis added.]”

See also MPEP §2164.06 (“Quantity of Experimentation”). Not only is any experimentation required here straight-forward, conventional and routine, but the specification also provides a reasonable amount of guidance with respect to the direction the experimentation should take. The determination of whether a particular combination of active ingredients is synergistic is a routine task well known to and commonly engaged in by persons skilled in this art. Moreover, they are accustomed to making many such determinations. It does not amount to undue experimentation for persons skilled in the art to do what they are accustomed to doing. Consequently, it would be undue experimentation for a person skilled in the art to screen, as is their custom, combinations of the active ingredients now claimed to determine whether they were synergistic. Accordingly, undue experimentation is not here implicated, and Applicants submit that the enablement is more than adequate for this particular art.

Rejections under 35 U.S.C. 103

The Examiner rejected claims 9, 11, 12 and 15 under 35 U.S.C. 103(a) as being obvious over Barnavon et al. (U.S. Patent No. 4,897,427) in view of Valcke (U.S. Patent No. 5,223,524). The Examiner found Barnavon teaches a composition comprising cyproconazole and the addition of a number of active ingredients to the composition.

The Examiner conceded Barnavon does not explicitly show a composition comprising cyproconazole "plus propiconazole or tebuconazole". The Examiner found it would have been obvious to make the instantly claimed composition comprising cyproconazole and propiconazole, because Barnavon suggests the composition wherein propiconazole is recited as an active ingredient that can be added. According to the Examiner, Valcke teaches a composition comprising tebuconazole and propiconazole. The Examiner found tebuconazole and propiconazole to be equivalent. Therefore, the Examiner found it would have been obvious to modify the composition in Barnavon to include the tebuconazole of Valcke to yield the instant claimed composition.

In response to the Examiner's rejection, Applicants again point out that the thrust of the rejection is directly rebutted by the evidence already of record. MPEP §716.02(a) recites the following, in part:

"A greater than expected result is an evidentiary factor pertinent to the legal conclusion of obviousness ...of the claims at issue." *In re Corkill*, 711 F.2d 1496, 226 USPQ 1005 (Fed. Cir. 1985)...Evidence of a greater than expected result may also be shown by demonstrating an effect which is greater than the sum of each of the effects taken separately (i.e., demonstrating "synergism")

In the present case, the Declaration of Dr. Martin Kugler, which is of the record and filed with Applicants' response on July 18, 2001, already shows that the combination of cyproconazole and propiconazole leads to a synergistic result, which synergistic result is

completely unexpected in view of the cited prior art of record. An additive effect, as the Examiner's proposed combination would suggest, would have resulted in a value of X equal to 1. Clearly the data do not support this contention. "Test 1" at page 2 of the Declaration shows that when cyproconazole and propiconazole are combined, they achieve a synergistic effect as indicated by the value of ' X ' equal to 0.67. Applicants submit this data directly rebuts the allegation that combining cyproconazole and propiconazole would have been obvious.

Applicants point out that the data in the Declaration additionally supports the claimed *synergistic* effect between cyproconazole and tebuconazole. Thus the data shows similar benefits with other claimed combinations, wherein "Test 2" at page 3 shows a synergistic effect when cyproconazole and tebuconazole are combined, as indicated by the value of ' X ' equal to 0.73. Thus, the data support a finding of unexpected and/or surprising results, whereby the claims as a whole are nonobvious by the combination of the cited references. *See* MPEP §716.02. Consequently, this rejection should be reconsidered and withdrawn on this basis alone.

The Examiner's basis for ignoring the unexpected results demonstrated appears to be that the ratios in the examples in the declaration are not supported by the instant specification. Respectfully, there is no requirement that the specification support ratios in a Rule 132 Declaration. The synergistic effect is not dependent on the ratios of the components. Moreover, there is absolutely no basis whatsoever in the law permitting an

Examiner to ignore any objective evidence of nonobviousness. As explained above, the data in the Kugler Declaration directly rebuts the thrust of the rejection. The Examiner took the position that it would have been obvious to combine cyproconazole plus tebuconazole or propiconazole because they had similar activities. The expectation would have been that a composition would have resulted with those activities added. The Kugler Declaration shows that the combination did not lead in the expected direction, but, instead, a synergistic result was achieved. Such result was completely unexpected given the Examiner's thrust of the rejection. Consequently, the Kugler Declaration directly rebuts the Examiner theory that the claimed combination would have been *prima facie* obvious.

Applicants would also point out that the claims require the improvement which is demonstrated, i.e., that the combination of cyproconazole and the second ingredient is synergistic. Consequently, the claims are exactly commensurate in scope with the improvement.

In view of the foregoing, Applicants submit that the Examiner would be fully justified to reconsider and to withdraw this rejection. An early notice that this rejection has been reconsidered and withdrawn is, therefore, earnestly solicited.

Conclusion

Applicants believe that the foregoing constitutes a bona fide response to all

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outstanding objections and rejections.

Applicants also believe that this application is in condition for immediate allowance. However, should any issue(s) of a minor nature remain, the Examiner is respectfully requested to telephone the undersigned at telephone number (212) 808-0700 so that the issue(s) might be promptly resolved.

Early and favorable action is earnestly solicited.

CONDITIONAL PETITION FOR EXTENSION OF TIME

If entry and consideration of the amendments above requires an extension of time, Applicants respectfully request that this be considered a petition therefor. The Commissioner is authorized to charge any fee(s) due in this connection to Deposit Account No. 14-1263.

ADDITIONAL FEE

Please charge any insufficiency of fees, or credit any excess, to Deposit Account No. 14-1263.

Respectfully submitted,

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By



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